

PATENT
Customer No. 22,852
Attorney Docket No. 2481.1801-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Heiner GLOMBIK *et al.*) Prior Group Art Unit: 1626
Application No.: Unassigned) Prior Examiner: RAMSUEL, Robert W.
Filed: Herewith)
For: DIARYLCYCLOALKYL)
DERIVATIVES, PROCESSES FOR)
THEIR PREPARATION AND)
THEIR USE AS)
PHARMACEUTICALS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed within three months of the filing date of the above-referenced application and before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents were previously submitted in a prior application, application no. 10/231,432, filed on August 30, 2002, upon which applicants rely for the benefits provided in 35 U.S.C. § 120. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: 
Carlos M. Tellez
Reg. No. 48,638

Dated: August 1, 2003

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1801-01000	Appln. No.	Not Yet Assigned
Applicant	Heiner GLOMBIK et al.		
Filing Date	Herewith	Group:	Not Yet Assigned

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	6,380,230	4/2002	Brodin et al.			
	6,342,512	1/2002	Kirsch et al.			
	6,245,744	6/2001	Frick et al.			
	6,221,897	4/2001	Frick et al.			
	6,221,633	4/2001	Ertl et al.			
	5,814,647	9/1998	Urban et al.			
	5,190,923	3/1993	Vincent et al.			
	3,174,901	3/1965	Sterne			

FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	98/08871	3/1998	PCT			
	97/26265	7/1997	PCT			
	99/03861	1/1999	PCT			
	97/41097	11/1997	PCT			
	01/91752	12/2001	PCT			
	00/63208	10/2000	PCT			
	WO 00/64876	11/2000	PCT			
	00/66585	11/2000	PCT			
	01/83451	11/2001	PCT			Abstract
	99/15525	4/1999	PCT			Abstract
	00/71549	11/2000	PCT			
	01/09111	2/2001	PCT			
	01/85695	11/2001	PCT			
	0 462 884	12/1991	EUROPEAN			
	00/40569	7/2000	PCT			
	00/78312	12/2000	PCT			
	97/28149	8/1997	PCT			

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1801-01000	Appln. No.	Not Yet Assigned
Applicant	Heiner GLOMBIK et al.		
Filing Date	Herewith	Group:	Not Yet Assigned

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	00/64888	11/00	PCT			
	00/64876	11/00	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Beck et al., "The Ontogeny Of Peroxisome-Proliferator-Activated Receptor Gene Expression In The Mouse And Rat," <u>Proc. R. Soc. Lond. B</u> , 247:83-87 (1992).
	OKADA et al., "Synthesis and Antitumor Activities of Prodrugs of Benzoylphenylureas," <u>Chem. Pharm. Bull.</u> , 42(1), 57-61 (1994).
	LEE et al., "Leptin Agonists as a Potential Approach to the Treatment of Obesity," <u>Drugs of the Future</u> , 26(9), 873-881 (2001).
	SALVADOR et al., "Perspectives in the Therapeutic Use of Leptin," <u>Expert Opin. Pharmacother.</u> , 2(10), 1615-1622 (2001).
	ZUNFT et al., "Carob Pulp Preparation for Treatment of Hypercholesterolemia," <u>Advances in Therapy</u> , 18(5), 230-236 (2001).
	MOTOJIMA, "Peroxisome Proliferator-Activated Receptor (PPAR): Structure, Mechanisms of Activation and Diverse Functions," <u>Cell Structure and Function</u> , 18, 267-277 (1993).
	TYLE, "Iontophoretic Devices for Drug Delivery," <u>Pharmaceutical Research</u> , 3(6), 318-326 (1986).
	HORIKOSHI et al., "Troglitazone--A Novel Antidiabetic Drug for Treating Insulin Resistance," <u>DDT</u> , 3(2), 79-88 (1998).
	DEMETRI et al., "Induction of Solid Tumor Differentiation by the Peroxisome Proliferator-Activated Receptor- γ Ligand Troglitazone in Patients with Liposarcoma," <u>Proc. Natl. Acad. Sci. USA</u> , 96, 3951-3956 (1999).
	ELSTNER et al., "Ligands for Peroxisome Proliferator-Activated Receptor γ and Retinoic Acid Receptor Inhibit Growth and Induce Apoptosis of Human Breast Cancer Cells <i>in vitro</i> and in BNX Mice," <u>Proc. Natl. Acad. Sci. USA</u> , 95, 8806-8811 (1998).
	SARRAF et al., "Differentiation and Reversal of Malignant Changes in Colon Cancer through PPAR γ ," <u>Nature Medicine</u> , 4(9), 1046-1052 (1998).
	DUNAIF et al., "The Insulin-Sensitizing Agent Troglitazone Improves Metabolic and Reproductive Abnormalities in the Polycystic Ovary Syndrome," <u>J. Clin. Endocrinol. Metab.</u> , 81(9), 3299-3306 (1996).
	LÖHRKE et al., "Detection and Functional Characterisation of the Transcription Factor Peroxisome Proliferator-Activated Receptor γ in Lutein Cells," <u>Journal of Endocrinology</u> , 159, 429-439 (1998).
	POYNTER et al., "Peroxisome Proliferator-Activated Receptor α Activation Modulates Cellular Redox Status, Represses Nuclear Factor- κB Signaling, and Reduces Inflammatory Cytokine Production in Aging," <u>J. Biol. Chem.</u> , 273(49), 32833-32841 (1998).

INFORMATION DISCLOSURE,CITATION

Atty. Docket No.	02481.1801-01000	Appln. No.	Not Yet Assigned
Applicant	Heiner GLOMBIK et al.		
Filing Date	Herewith	Group:	Not Yet Assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	PINEDA-TORRA et al., "Peroxisome Proliferator-Activated Receptor Alpha in Metabolic Disease, Inflammation, Atherosclerosis and Aging," <i>Curr. Opinion in Lipidology</i> , 10, 151-159 (1999).
	COLVILLE-NASH et al., "Inhibition of Inducible Nitric Oxide Synthase by Peroxisome Proliferator-Activated Receptor Agonists: Correlation with Induction of Heme Oxygenase 1," <i>Journal of Immunology</i> , 161, 978-984 (1998).
	STAELS et al., "Activation of Human Aortic Smooth-Muscle Cells is Inhibited by PPAR α but not by PPAR γ Activators," <i>Nature</i> , 393, 790-793 (1998).
	GREEN, "Receptor-Mediated Mechanisms of Peroxisome Proliferators," <i>Biochemical Pharmacology</i> , 43(3), 393-401 (1992).
	GÖTTLICHER et al., "Fatty acids Activate a Chimera of the Clofibrate Acid-Activated Receptor and the Glucocorticoid Receptor," <i>Proc. Natl. Acad. Sci. USA</i> , 89, 4653-4657 (1992).
	SCHOONJANS, "Peroxisome Proliferator-Activated Receptors, Orphans with Ligands and Functions," <i>Current Opinion in Lipidology</i> , 8, 159-166 (1997).
	SCHMIDT et al., "Identification of a New Member of the Steroid Hormone Receptor Superfamily that is Activated by a Peroxisome Proliferator and Fatty Acids," <i>Molecular Endocrinology</i> , 6, 1634-1641 (1992).
	AMRI et al., "Cloning of a Protein That Mediates Transcriptional Effects of Fatty Acids in Preadipocytes," <i>J. Biol. Chem.</i> , 270(5), 2367-2371 (1995).
	FRICK et al., "Prevention of the Angiographic Progression of Coronary and Vein-Graft Atherosclerosis by Gemfibrozil After Coronary Bypass Surgery in Men with Low Levels of HDL Cholesterol," <i>Circulation</i> , 96, 2137-2143 (1997).
	DE FAIRE et al., "Retardation of Coronary Atherosclerosis: The Bezafibrate Coronary Atherosclerosis Intervention Trial (BECAIT) and Other Angiographic Trials," <i>Cardiovasc. Drugs Ther.</i> , 11, 257-263 (1997).
	LEHMANN et al., "An Antidiabetic Thiazolidinedione Is a High Affinity Ligand for Peroxisome Proliferator-activated Receptor γ (PPAR γ)," <i>J. Biol. Chem.</i> , 270(22), 12953-12956 (1995).
	ELBRECHT et al., "Molecular Cloning, Expression and Characterization of Human Peroxisome Proliferator Activated Receptors $\gamma 1$ and $\gamma 2$," <i>BBRC</i> , 224, 431-437 (1996).
	FORMAN et al., "15-Deoxy- $\Delta^{12, 14}$ -Prostaglandin J $_2$ Is a Ligand for the Adipocyte Determination Factor PPAR γ ," 83, 803-812 (1995).
	KLIEWER et al., "A Prostaglandin J $_2$ Metabolite Binds Peroxisome Proliferator-Activated Receptor γ and Promotes Adipocyte Differentiation," <i>Cell</i> , 83, 813-819 (1995).
	STAELS et al., "Role of PPAR in the Pharmacological Regulation of Lipoprotein Metabolism by Fibrates and Thiazolidinediones," <i>Curr. Pharm. Des.</i> , 3(1), 1-14 (1997).
	FRUCHART et al., "PPARS, Metabolic Disease and Atherosclerosis," <i>Pharmacol. Research</i> , 44(5), 345-352 (2001).
	KERSTEN et al., "Roles of PPARs in Health and Disease," <i>Nature</i> , 405, 421-424 (2000).

INFORMATION DISCLOSURE/CITATION

Atty. Docket No.	02481.1801-01000	Appn. No.	Not Yet Assigned
Applicant	Heiner GLOMBIK et al.		
Filing Date	Herewith	Group:	Not Yet Assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	PINEDA-TORRA et al., "Peroxisome Proliferator-Activated Receptors: From Transcriptional Control to Clinical Practice," Curr. Opin. Lipidol., 12, 245-254 (2001).
	ASAKAWA et al., "Cocaine-Amphetamine-Regulated Transcript Influences Energy Metabolism, Anxiety and Gastric Emptying in Mice," Hormone & Metabolic Research, 33, 554-558 (2001).
	Vidal-Puig et al., "Regulation of PPAR γ Gene Expression By Nutrition And Obesity In Rodents," J. Clin. Invest., 97(11):2553-2561 (1996).
Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449 400201-1	Patent and Trademark Office - U.S. Department of Commerce